ADMINISTRATIVE INFORMATION

Manufacturer Name:	Kensey Nash Corporation 735 Pennsylvania Drive Exton, PA 19341
Official Contact:	Cindy R. Varughese, RAC Regulatory Affairs Specialist Kensey Nash Corporation Telephone: (484)-713-2174 Fax: (484)-713-2903
Date Prepared:	December 20, 2007

DEC 3 1 2007

DEVICE NAME

Classification Name:	Surgical Mesh
Trade/Proprietary Name:	Kensey Nash Bioresorbable Surgical Mesh

ESTABLISHMENT REGISTRATION NUMBER

2530154

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 878.3300, Surgical Meshes are polymeric screens intended to be implanted to reinforce soft tissues. These devices are classified as Class II. Surgical Meshes have been assigned Product Code FTL.

INTENDED USE

The Kensey Nash Bioresorbable Surgical Mesh is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. Tissue attachment to the bioresorbable surgical mesh is minimized in case of direct contact with the viscera.

DEVICE DESCRIPTION

The Kensey Nash Bioresorbable Mesh is a biodegradable surgical mesh for trauma and reconstructive surgical procedures involving soft tissues. The Kensey Nash Bioresorbable Mesh is available in various sizes and thickness for use in maintaining the relative position of healing tissues. The implants maintain the stability of soft tissues during the healing period and minimize the attachment of tissue to the device. The Kensey Nash Bioresorbable Mesh material is subsequently reabsorbed by the body once the soft tissues have healed. The implants are not intended for use where permanent implants are required.

Material

The Kensey Nash Bioresorbable Mesh is made from the amorphous biodegradable copolymer 70:30 poly (L-lactide-co, DL-lactide). This copolymer degrades and resorbs in vivo by hydrolysis and is metabolized by the body into CO_2 and H_2O.

In Vitro Testing

The Kensey Nash Bioresorbable Surgical Mesh is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures. Testing has shown that inherent viscosity remains within an appropriate range over 120 minutes when heated to 60°C in saline. The relatively brief exposure anticipated during the surgical preparation of Kensey Nash Bioresorbable Surgical Mesh is not expected to have a significant effect on its mechanical properties. Aging and mechanical testing shows that the device material is adequate for the indications for use and substantially equivalent to the predicate devices.

In Vivo Testing

The animal studies have shown that the device material is safe and efficacious for the indications for use.

EQUIVALENCE TO MARKETED PRODUCT

The Kensey Nash Bioresorbable Surgical Mesh shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: MacroPore Surgi-Wrap (TS) and the MacroPore Surgi-Wrap MAST; Class II medical devices that were cleared for marketing in the United States under K012025 and K031955, respectively.

Indications For Use

The Kensey Nash Bioresorbable Surgical Mesh shares identical indications for use principles with the predicate devices, as both the Kensey Nash Bioresorbable Surgical Mesh and the predicate devices are indicated for the same surgical procedures.

Design and Materials

The physical designs of Kensey Nash Bioresorbable Surgical Mesh and the predicate devices (MacroPore Surgi-Wrap and the MacroPore Surgi-Wrap MAST) are substantially equivalent, consisting of thin, semi-rigid, bioresorbable sheets manufactured by the same process and fabricated from the identical bioresorbable PLA raw material. The Kensey Nash Bioresorbable Surgical Mesh and the predicates also share design features of allowing for contouring. The device and the MacroPore Surgi-Wrap predicate are fully contourable when heated to approximately 55°C. The thickness of the predicate devices and the Kensey Nash Bioresorbable Surgical Mesh are substantially equivalent, as the thinnest device thickness is identical to the Surgi-Wrap predicate (0.02mm). The shapes and sizes of the predicate devices and the Kensey Nash Bioresorbable Surgical Mesh are also substantially equivalent, as they are rectangular sheets provided in size ranges from 25mm x 25mm to 500mm x 500mm with thickness ranges from 0.02mm to 1.0mm. The mechanical characteristics of the device are substantially equivalent to the predicate devices with respect to mechanical strength. In addition to physical characteristics, both the predicate devices and the Kensey Nash Bioresorbable Surgical Mesh can be cut to specific shapes and sizes by the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 1 2007

Kensey Nash Corporation
% Ms. Cindy Varughese, RAC
Regulatory Affairs Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K071695
Trade/Device Name: Kensey Nash Bioresorbable Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: December 21, 2007
Received: December 26, 2007

Dear Ms. Varughese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

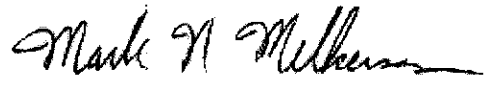
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K071695

Device Name: **Kensey Nash Bioresorbable Surgical Mesh**

Indications for Use:

The Kensey Nash Bioresorbable Surgical Mesh is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. Tissue attachment to the bioresorbable surgical mesh is minimized in case of direct contact with the viscera.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR MARK MELKERSON

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071695